

*Application/Control Number: 10/091,360; filed 05-04-2002
Page 8 of 12*

Art Unit: 1631

III. REMARKS

Amendments Made Herein and Summary of Status of Claims:

The claims 13-15, and 17 are amended, and independent claim 44 has been newly added to replace claim 38. New claim 45, dependent from claim 44, has been added to replace claim 39. Claims 1-12, 19-39, and 42 and 43 are cancelled without prejudice.

Rejections

Claim Rejections-35 USC 112

Claims 13-18, 31-34, and 36-43 are rejected under 35 USC 112, second paragraph, as indefinite. Specifically, the Examiner objects to insufficient antecedents.

Applicant respectfully traverses the rejections of the claims as presently amended. On the contrary, the rejection of cancelled claims 38 and 39, as well as 31-33, 36 and 37, is believed moot. Claims 13-15 and 17 have been amended in accordance with the Examiner's suggestions.

Applicant requests that the rejections under the statute be withdrawn.

Claim Rejections -35USC 102

Claims 38, 39, and 40-43 are rejected under 35 USC 102(a) as anticipated by WO 97/20198 (Douglas et al.). Specifically, the Examiner alleges that Douglass discloses an automated cell analysis method that may be used for rare cell identification.

Applicant respectfully traverses the rejection. On the contrary, the cited reference to Douglass neither discloses nor even suggests the presently amended claims. Applicant

Application/Control Number: 10/091,360; filed 05-04-2002
Page 9 of 12

Art Unit: 1631

respectfully traverses the Examiner's 35 U.S.C. §102(a) rejections asserting in part that the reference of record does not teach every element of any claim. Applicant respectfully notes that anticipation requires that each and every element of the claimed invention be disclosed in the prior art reference, device, or practice (See, *Akzo N. V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986) as set forth below. Moreover, Applicant respectfully traverses the Examiner's anticipation rejection based in part upon the claim including elements that find no counterpart in the cited reference. As presently claimed in claim 44, the invention is directed to a computer-controlled method for rare cell image identification, comprising the steps of: (i) isolating a sample comprising cells from a body fluid or tissue; (ii) fixing said sample comprising rare cells in cell aggregates (blobs) in a monolayer on a substrate; (iii) precisely locating a rare cell candidate in said blob and continuously recording x, y and z- coordinates thereof with a computer-controlled mobile microscope system searching said optical field starting from an initial position on an optical field of said monolayer; (iv) receiving a color image signal of said rare cell candidate in said monolayer sample; (v) computer-implemented transforming the color image signal from a native color of Red, Green and Blue (RGB) to a binary quantized Hue, Luminescence and Saturation (HLS) signal; (vi) enhancing detection of said rare cell color image by applying different computer implemented HLS signal masks with selectively limiting pixel values; (vii) identifying said rare cell candidate by automatically measuring pre-set criteria in terms of size of a cell or cell nucleus, characteristic cell markers; and (viii) automatically locating by a selective tag dispensing system which is programmed to tag selectively said rare cell in situ to determine biological criteria comprising genomic variation, mutation, or chromosomal

*Application/Control Number: 10/091,360; filed 05-04-2002
Page 10 of 12*

Art Unit: 1631

aberration.

In the first instance, the cited reference is silent on a systematic programmed survey of the microscope sample. Moreover, the prior art does not reasonably predict a fully automated system which provides an automatically tag for identification and diagnosis of the relevant rare cell candidate in the monolayer of the microscope (see paragraphs 194 and 195). In addition, the reference does not even remotely suggest simultaneous use of a plurality of microscopy objectives (claim 40). As admitted by the Examiner, Applicant respectfully asserts that Douglass does not disclose the instant rare cell mask nor its filtering by histogram analysis as claimed in instant claims 13-15. Therefore, the claimed method is believed free of the cited reference and allowance thereof is requested.

Rejection-35 USC 103

Claims 13-18, 31-34 and 36-39 are rejected under 35 USC 103(a) as obvious over WO 97/20198 to Douglass et al. combined with Glasbey et al. (Image Analysis for the Biological Sciences (1995) John Wiley and Sons, Chichester, England. Pages 31-33. Specifically, the Examiner admits that Douglass is deficient in filtering by histogram analysis as presently claimed, but alleges that the secondary reference to Glasbey discloses the lacking methodology suggesting the instant method. Claims 31-34 and 36-37 are cancelled rendering this rejection moot. Claims 38 and 39 have been replaced by new claims 44, 45 and 46.

Applicant respectfully asserts that the presently claimed method is neither disclosed nor even suggested by the combined references. On the contrary, Applicant respectfully asserts that the instant automatic application of filtering masks for the enhancement of rare cell imaging combined with a simultaneous tagging operation is not

*Application/Control Number: 10/091,360; filed 05-04-2002
Page 11 of 12*

Art Unit: 1631

reasonably predicted by the cite art. The presently claimed method affords an advantageous selection rare cell image and identification thereof so as to rapidly and automatically determine the biological criteria comprising genomic variation, mutation, or chromosomal aberration in a fetal cell. Thus, the *prima facie* case of obviousness has not been made.

In view of the amendment and remarks set forth above Applicant respectfully asserts that the rejections of the claims 13-18, 31-34 and 36-39 under 35 USC 103 is deemed improper, and should be withdrawn, which favorable action is requested.

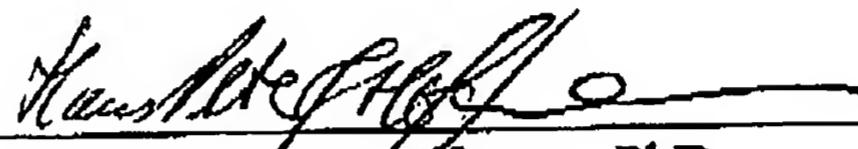
Application/Control Number: 10/091,360; filed 05-04-2002
Page 12 of 12

Art Unit: 1631

CONCLUSIONS

An early notice of allowance in the next Office action is earnestly requested.

Respectfully submitted,



Date: August 9, 2006

Hans-Peter G. Hoffmann, PhD
Agent for Applicant, Reg. No. 37,352
Kelley Drye & Warren LLP
Two Stamford Plaza
281 Tresser Boulevard
Stamford, CT 06901
Tel.: 203-351-8011
Fax: (203) 327-2669
E-mail: hhoffmann@kellydrye.com

CTO1/HOFFMANN/230537.1